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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,109	01/26/2001	Allan S. Lau	4099-0003.31	8965
22918	7590	06/27/2005	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			WINKLER, ULRIKE	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/772,109	Applicant(s) LAU ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5.02

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 24, 2005 has been entered.

Claims 1-3, 5-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Priority

This application is a CIP of application 09/657881 and the provisional application 60/152854, claims that make reference to CrmA will only be granted the priority to the filing date of the instant application which is January 26, 2001.

Claim Rejections - 35 USC § 103

The rejection of claims 1-8, 11, 12, 25, 26, 29-34 and 37-40 under 35 U.S.C. 103(a) as being unpatentable over Dixit (U.S. Pat. No. 6,159,712), Lau et al. (U.S. Pat. No. 6,159,712) and Suzuki et al. (Derwent Abstract XP-002170158; see IDS Paper No. 13; JP9-163983-A see PTO 892 translation of full patent included) **is maintained** for reasons of record.

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Applicants' arguments and the Offices response are essentially the same of record. Applicants' arguments are that there is no motivation to combine the references and that the references teach away ("the combination would be contrary to the express purpose of the teachings of Dixet") from making the composition as claimed. Applicants' arguments have been fully considered but are not persuasive for reasons of record. In contrast to applicant's assertions; disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See *In re Susi* USPQ 423 (CCPA 1971). A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use. See *In re Gurley* 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). ["Gurley's position appears to be that a reference that "teaches away" can not serve to create a *prima facie* case of obviousness. We agreed that this is a useful general rule. However, such a rule can not be adopted in the abstract, for it may not be applicable in all factual circumstances."] Although a reference that teaches away is a significant factor to be considered in determining unobviousness, the nature of the teaching is highly relevant, and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use. In this case the Dixit cells have increased resistance to apoptosis by having increased expression of crmA in the cells. Applicants arguments have been fully considered but they fail to persuade, and the rejections are maintained for reasons of record.

In this case, Suzuki et al. does more than just merely teach the prevention of apoptosis in a cell. The teachings of Susuki et al. are directed to the increase in the ability of a cell to produce useful matter (product), such as cytokines, by preventing apoptosis from killing the cell

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prematurely. The increased cell life translates into an increased production of the product (see paragraph 0021). The reference teaches the use of a cell line into which an apoptosis inhibiting gene has been introduced, such as CrmA. Dixit V.M. teaches the transformation of MCF7 and BJAB cells (human derived cells line) with a vector encoding Crm-A (see examples 3, 4 and 5). It would have been obvious to one of ordinary skill in the art to utilize the cell line taught by Dixit for the production of useful matter, such as a cytokine, as taught by Suzuki et al. Suzuki et al. also establishes that those cells that contain the apoptosis inhibiting gene produce more protein when compared to cells that do not have the gene insert, the level of protein production doubled at day 7 and tripled at day 14 (see figure 9, Suzuki et al.). In considering the teachings of Dixit and Suzuki et al. one of ordinary skill in the art would have had a high expectation of success in using the cell line of Dixit for the production of useful matter, such as a cytokine, given the teaching of Suzuki et al. So the combination of Suzuki et al. and Dixit teaches the use of a CrmA expressing cell for the production of useful matter. Lau et al. teaches a method of producing a cell that is able to overexpress cytokines wherein the cell comprises a vector containing PKR, and the cytokine expression is stimulated by induction using poly I:C and the priming agent PMA. Overexpression of PKR induced overproduction of the cytokines INF-alpha and INF-beta.

MPEP 2144.06 "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

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The instant invention is drawn to a composition, a cell line (claim 1) which can produce a cytokine. This cell line expresses a coding sequence for an anti-apoptotic protein, specifically CrmA (claims 2).

For this office action, the preamble of the product-by-process claims were interpreted as “a composition of matter” (which are *products*). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P.

Section 2113 states that:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Therefore, it remains the Offices position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the antiapoptotic protein CrmA with the PKR cell line, both of which are capable of overexpressing cytokines (products). Suzuki et al. suggest the use of combining an apoptosis-suppressive gene including CrmA for the production of cytokines and Lau teaches that the PKR cell line can overexpress a cytokine. One having ordinary skill in the art would have been motivated to include CrmA with the PKR cell line because both can be used for the expression of proteins (cytokines), as taught by Lau and Suzuki et al. Therefore, the instant invention is obvious over of Dixit, Lau et al. and Suzuki et al.

Conclusion

No claims allowed.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.



ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER

6/23/05